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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,531	03/23/2004	David Feygin	115-003US	4765

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EXAMINER	
CRABTREE, JOSHUA DAVID	
ART UNIT	PAPER NUMBER
3714	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,531	FEYGIN ET AL.	
	Examiner	Art Unit	
	Joshua D. Crabtree	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 23 March 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/23/04,6/27/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the limitation "said bevel". There is insufficient antecedent basis for this limitation in the claim. Further, the term "wherein a data processing system" should be recited as --further comprising a data processing system--, so as to clarify the confusion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5, 10-17, and 20-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (US 6,470,302).

With regard to claim 1, and the limitations of a need and a catheter, wherein the catheter receives the needle, Cunningham et al. disclose this feature (Col. 5: 34-37). With regard to the limitation of a sensor, wherein the sensor senses an orientation of at least one of a feature of the

needle or a feature of the catheter, Cunningham et al. disclose that the interface device includes encoders to measure motion of the catheter needle assembly (Col. 5: 55 – Col. 6: 11).

With regard to claims 3, and the limitation wherein the sensor resolves orientation of the feature in at least one direction (as in claim 3). Cunningham et al. disclose that potentiometers and encoders may be located at various parts of the instrument to detect motion (Col. 8: 1-37 - Col. 9: 37- Col. 10: 17).

With regard to claim 5, and the limitation wherein the sensor is physically coupled to the needle, Cunningham et al. disclose this feature (Col. 8: 30-37).

With regard to claims 10 and 11, and the limitations wherein the needle and catheter are disposed completely outside of a housing until inserted therein by a user to simulate a vascular access procedure (as in claim 10), and wherein the needle and catheter are inserted through pseudo skin to simulate a vascular access procedure (as in claim 11), Cunningham et al. disclose that it is known in the art to use a model or mock-up of human anatomy for insertion of a catheter, for simulation of vascular access procedures (i.e., a housing or pseudo-skin external to the needle and catheter) (Col. 1: 51 – Col. 2: 35).

With regard to claim 12, and the limitations of a pseudo skin, and a force-feedback assembly, wherein the force-feedback assembly is disposed beneath the pseudo skin, Cunningham et al. disclose that a simulation of human skin is presented, and force feedback is provided to simulate how the device would feel if a user were using the device on an actual patient (Col. 7: 6-20).

Additionally, Cunningham et al. disclose a skin traction mechanism, which resembles human skin, and contains a force feedback assembly underneath (Col. 7: 20-35; Fig. 7).

With regard to claims 12-14, and the limitations of an end effector, wherein the end effector comprises a needle (as in claim 13), and wherein the end effector comprises a catheter (as in claim 14), and wherein the end effector reversibly couples to the force feedback assembly (as in claim 12), Cunningham et al. disclose a needle and catheter, as previously described (Col. 5: 55 – Col. 6: 11). The catheter assembly is couple with the force feedback assembly (*Catheter assembly 34 shown in Fig. 4; Catheter is connected to the system in Fig. 3; Col. 7: 6-20*).

With regard to claims 15 and 16, and the limitation of a data processing system, wherein the force-feedback assembly receives a control signal from the data processing system (as in claim 15), and wherein signals indicative of a position of the end effector are transmitted to the data processing system (as in claim 16), Cunningham et al. disclose this feature (Col. 9: 37 – Col. 10: 17). Additionally, Cunningham et al. disclose that this feature is known in the art (Col. 4: 45-58).

With regard to claim 17, and the limitation of a housing, wherein the force-feedback assembly is disposed within the housing, Cunningham et al. disclose this feature (Col. 10: 3-5).

With regard to claim 20, 24, and 25, and the limitation of an end effector (as in claim 20), wherein the end effector comprises a catheter (as in claim 24), wherein the end effector comprises a needle (as in claim 25), Cunningham et al. disclose theses features, as previously described (Col. 5: 55 – Col. 6: 11).

With regard to claim 20, and the limitation of a pseudo skin, wherein the pseudo skin has a first side and a second side, and wherein the end effector is disposed on the first side of the pseudo skin, Cunningham et al. disclose simulating human skin, for use with the catheter assembly (Col. 7: 5-20). With regard to the limitation of a receiver for receiving the end effector,

wherein the receiver is disposed on the second side of the pseudo skin, Cunningham et al. disclose that a force feedback mechanism is located beneath the simulation of skin, in order to provide feedback to a user while operating with the catheter assembly (Col. 7: 5-20).

With regard to claim 21, and the limitation of a housing, wherein the receiver is disposed within the housing, Cunningham et al. disclose this feature (Col. 10: 3-5). With regard to the limitation wherein the pseudo skin is substantially co-planar with a surface of the housing, Cunningham et al. disclose a housing (Fig. 3). The catheter assembly (Item 34 in Fig. 3) interacts with the simulated skin inside the housing. By looking at Fig. 3, one can see that the surface of the simulated skin would be co-planar with the top surface of the housing.

With regard to claim 22, and the limitation wherein the pseudo skin comprises an opening, and wherein, to simulate a vascular access procedure, the end effector is inserted through the opening and removably coupled to the receiver, Cunningham et al. disclose that this feature is known in the art (Col. 1: 50 – Col. 2: 35).

With regard to claim 23, and the limitation wherein the receiver has at least one rotational degree of freedom and at least one translation degree of freedom, Cunningham et al. disclose that degrees of freedom of rotation and translation are measured (Col. 9: 20- Col. 10: 17).

With regard to claims 26 and 27, and the limitations wherein the end effector comprises a sensor (as in claim 26), and wherein the sensor senses an orientation of the end effector, Cunningham et al. disclose this feature, as previously described (Col. 9: 36 – Col. 10: 17).

With regard to claim 28, and the limitation of a data processing system, wherein the data processing system receives a signal that is indicative of the orientation of the end effector,

Cunningham et al. disclose that a computer system may receive the motion information pertaining to the catheter assembly (Col. 10: 5-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 2, 6-8, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Grayzel (US 4,850,960).

With regard to claims 2, 6-8, 18, and 19, Cunningham et al. disclose that potentiometers and encoders may be located at various parts of the instrument to detect motion (Col. 8: 1-37 - Col. 9: 37- Col. 10: 17) and the instrument may be interfaced with a computer system (Col. 5: 29-34; Col. 6: 45- Col. 7: 20; Fig. 1). Cunningham et al. do not explicitly disclose the feature wherein the needle or catheter comprises a bevel (as in claims 2, 6, 7, 18 and 19). Grayzel teaches the feature of a catheter with a bevel tip (Figs. 4A-D). Grayzel teaches that a bevelled tip helps to facilitate insertion of the catheter into a pre-existing puncture aperture (See abstract), and can ease introduction of the catheter through muscle walls (Col. 4: 1-5), as well as providing other advantages (Col. 4: 6-35). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Grayzel into the invention of Cunningham et al. in order to provide the aforementioned advantages.

With regard to claim 18, and the limitation wherein the needle-catheter module includes a needle, and a catheter, wherein the catheter receives the needle, Cunningham et al. disclose this feature, as previously described (Col. 5: 55 – Col. 6: 11). With regard to the limitation of a sensor, wherein the sensor senses an orientation of the bevel, Cunningham et al. disclose sensors to measure the position and motion of the catheter (Col. 9: 37 – Col. 10: 17).

With regard to claim 19, and the limitation of a data processing system, wherein the data processing system receives a signal indicative of the orientation of the bevel, Cunningham et al. disclose that a computer system may receive the motion information pertaining to the catheter assembly (Col. 10: 5-17).

4. **Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Hunter et al. (US 2004/0097806).**

With regard to claim 4, Cunningham et al. do not explicitly disclose the limitation wherein the sensor comprises a MEMS device. Hunter et al. teach the feature of a catheter with a MEMS device, and that a MEMS device helps to provide a controllable and storable catheter (Paragraph [0071]). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Hunter et al. into the invention of Cunningham et al. in order to provide the aforementioned advantage.

5. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 6,470,302) in view of Cunningham et al. (US 2002/0163497) (*hereafter referred to as Cunningham-2*).**

With regard to claim 9, Cunningham et al. do not disclose the limitation wherein the signal is transmitted wirelessly to the data processing system. Cunningham-2 teach a haptic interface system in which signals may be transmitted wirelessly from a haptic interface device to a computer (Paragraph [0081]). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Cunningham-2 into the invention of Cunningham et al. in order to provide a haptic interface system capable of transmitting signals wirelessly from a haptic device to a computer. This feature could be advantageous in a training environment, in that it would help prevent accidents from occurring, such as tripping over cables.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Barnes et al. (US 6,038,488) disclose a catheter simulation device.

Pugh (US 2003/0031993) discloses a medical examination teaching and measurement system..

Mor (US 6,088,020) discloses a haptic device.

Rosenberg et al. (US 5,821, 920) disclose a control input device for interfacing an elongated flexible object with a computer system.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joshua D. Crabtree whose telephone number is 571-272-8962. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joe H. Cheng
Primary Examiner

Joshua D. Crabtree
March 20, 2007